



Australian Government

Department of Health

National Industrial Chemicals

Notification and Assessment Scheme

Transcript – NICNAS to AICIS

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National Industrial Chemicals Notification and Assessment Scheme

NICNAS

Web: www.nicnas.gov.au

Email: info@nicnas.gov.au

Phone: 1800 638 528

Phone: +61 02 8577 8800

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Slide 1

Hello! This video will provide a general overview on the journey to a new regulatory framework for industrial chemicals.

Now it's been a long and winding road but we're finally, nearly there. We're about to close the door on NICNAS (the National IC N and A Scheme) and step into the new world of AICIS (the Australian IC Introduction Scheme). This presentation aims to give you an overview of what that means in practical terms.

Slide 2

On the 1st of July it'll be a new day, and a new scheme, with the same Mission – to protect human health and the environment. Right now we'll start with a general outline of how the new scheme is built: what the different functions of the scheme are; what the underlying principles are; and the key similarities and differences between NICNAS and AICIS.

Slide 3

Here are the main functions of AICIS, most of which might sound familiar to anyone who's dealt with NICNAS. Most of these will be covered in a bit more detail later in this presentation, and each of them will be covered in a lot more detail in their own dedicated presentations.

Starting at the top and going clockwise, our first key function is registration of introducers, so we know who's introducing industrial chemicals into Australia.

Our second key function here is 'assessment of applications', which in the new scheme includes applications where necessary for pre-market risk assessment, and applications for protection of Confidential Business Information from publication.

Our third key function is Evaluations, which is a new piece of terminology for the new scheme, which broadly encompasses post-market risk assessment activities similar to those currently being done under NICNAS.

Next are 'risk management referrals' and 'publication of information', which are related in that they are the way our risk assessment work is translated into external value. We use our risk assessment conclusions about industrial chemical introductions to make risk management recommendations, which we publish and also refer directly to the relevant risk management bodies responsible for the safe use of industrial chemicals. We also publish more broadly information about industrial chemicals that will help protect human health and the environment.

Coming around to the left side of the wheel we have the function of Inventory management, the Inventory being of course a central and critical feature of the regulatory framework now and in the future, as it defines the regulatory treatment for industrial chemical introductions based on its listings.

And the last 2 major functions are also related: Post-introduction monitoring and Compliance activity. The new scheme features a much fuller range of monitoring and enforcement powers and actions available to the regulator, to accompany a more risk-proportionate approach to regulatory effort.

Slide 4

Now we have a couple of slides outlining the Principles upon which the new scheme is based. The first and foremost of these, which pretty well underscores all the others, is the notion of 'risk proportionate regulation'. By using risk as the basis for directing our regulatory effort, we can re-balance our regulatory controls so that our pre-market (or pre-introduction) assessment is focused on higher risk introductions, and this is accompanied by greater post-market (post-introduction) monitoring and a framework for comprehensive processes for evaluating chemicals already in use, including the ability to take prompt action should new information about chemical risks become available. In this way we aim to incentivise lower risk chemical introductions.

Slide 5

Here are the rest of our major Principles, all still underscored by the overarching Principle of risk-proportionality:

AICIS will be a risk assessor, not a risk manager. However, the new scheme will include certain 'last resort' powers of risk management, only available for use when there is a risk that cannot be managed any other way, by any other agency. In the new scheme the ED can effectively 'ban' a chemical, but only as a last resort (and with substantial checks and balances).

As mentioned earlier, the new scheme will have at its disposal the full range of graduated compliance powers (rather than the choice between a severely worded letter and a prosecution), to allow for risk-proportionate compliance action.

One area that features a quite new approach is the publication and protection of information relating to industrial chemical introduction. The new scheme seeks to publish the information of value in protecting human and the environment from chemical risks, while protecting commercial information that is not necessary for that purpose.

We will also be continuing our ongoing quest for greater use of trusted international risk assessments, to reduce regulatory burden. As well as continuing our current practice of using international materials to inform (and reduce the burden of) our own risk assessments, introducers will be able to use international assessments from trusted overseas bodies to allow immediate introduction where the risks are the same as overseas and can be managed in a comparable way.

Finally, a new and developing Principle for AICIS is the restriction of our use – and the ability of introducers to use – data from testing on animals for ingredients used in cosmetic products.

Slide 6

This slide highlights the things about the new scheme that are the same as the current scheme.

We will continue to regulate 'industrial chemicals', and the definition of an industrial chemical will still be made by exclusion, that is, an industrial chemical is a chemical that is NOT a therapeutic, a food, an agricultural or veterinary chemical. We will continue to regulate at the point of introduction into Australia, be that by importation or by domestic manufacture, and our role will continue to be assessing risks and making recommendations

for management of those risks (notwithstanding the 'risk manager of last resort' new powers mentioned earlier).

All of this is in pursuit of the same primary goal, to protect the health and environment of the Australian people.

Slide 7

This diagram demonstrates the unchanging interfaces between the new scheme and the other Commonwealth chemical regulators: therapeutics will go on being regulated by the Therapeutic Goods Administration, foods by Food Standards ANZ, and agricultural and veterinary products by the APVMA.

Slide 8

Now here are the things that are going to change.

OK the first one is the obvious one, but also contains a meaningful message: the current scheme is called NICNAS and focuses on pre-market notification and assessment; the new scheme is called AICIS and focuses more broadly on risk-proportionate regulation of industrial chemical introduction.

Next, we have a title change for the head of the scheme; however it'll be the same person doing the job.

The chemical Inventory has a title change too, and more changes besides, which we'll come to later.

The next 4 points are terminology changes that also indicate a change in approach. In particular, and importantly, the new scheme focuses on introductions, not just on chemicals – this is in order to focus on risk, which comprises hazard and exposure, i.e. the introduction and use of the chemical, not just the innate characteristics of the chemical considered in isolation. So instead of 'existing chemicals' (being chemical on NICNAS's Inventory), we'll have 'listed introductions', being introductions in accordance with the terms of a listing on AICIS's Inventory. The flipside of those will be, instead of 'new chemicals', 'unlisted introductions'.

As I mentioned earlier, there'll be an entirely new approach to protecting confidential business information, so no more 'exempt information', but rather protected CBI.

And the last point here is that we won't have 'notifiers' making 'notifications' any more, but rather 'applicants' for various items.

Slide 9

Here are some more key changes.

We won't be issuing permits any more. We will retain a separate authorisation category for commercial (that is, non retail) evaluation.

There'll be no more Confidential section of the Inventory, but rather listings all on the one Inventory, some of which will have protection CBI (that's confidential business information).

In the new scheme, a framework for post-introduction 'evaluations' will cover activities that are currently constrained by overly prescriptive legislative processes, namely the processes

for secondary notification and assessing Priority Existing Chemicals, and will also cover what is currently an administrative program of assessing chemicals on our Inventory, known as IMAP. Certain aspects of secondary notification will also be replaced in the new scheme by information obligations, and pathways to apply for variation of Inventory listings, or of the terms of certificates.

Slide 10

In this last slide describing the overall framework we're moving into, we come to the chemical Inventory. AICIS's Inventory will explicitly be an Inventory of industrial chemicals. It may be surprising to note that NICNAS's Inventory, the AICS, is not an Inventory of exclusively industrial chemicals. Because of this, there's transitional legislation that stops the non-industrial chemicals from being included on the new Inventory, and NICNAS has engaged in a process to identify non-industrial chemicals on the AICS for this purpose.

Listings on the new Inventory will include links to statements of the conclusions of any risk assessments AICIS has completed.

Finally, the new Inventory has entirely new means of protecting confidential business information.

There'll be a lot more detail about the Inventory in a separate presentation dedicated to that topic. There's also a presentation that goes into the ins and outs of 'transitional arrangements', that is, the legislated pathways to get your current authorisations and entitlements under NICNAS duly recognised under AICIS.

Slide 11

Now we're going to look at the new scheme through the lens of introducer obligations – what do you have to do, and when do you have to do it, and how that changes from what you're used to with NICNAS.

Slide 12

So here's another nifty circular diagram for you. This time we'll move clockwise around the sequence of introducer obligations.

Just looking at them quickly in order, we start with all industrial chemical introducers having to register with the regulator. Then at step 2, you need to know some details about the chemicals you're introducing, which leads you to step 3, where you have to understand the category that each chemical introduction falls into – this is a critical new concept in the new scheme, which we'll spend more time on, and another whole presentation coming up.

Then, depending how your introductions are categorised, you may need to apply to AICIS for a pre-introduction risk assessment, or for other kinds of introductions you might need to submit a report or declaration, either before or after the introduction.

Finally, you'll need to keep certain records relating to your introductions, and you may be obliged to give us information that we ask for in specific circumstances set out in the legislation.

Now let's look at each section of this wheel of obligations in turn.

Slide 13

The obligation to register as a chemical introducer will remain unchanged, for all importers or manufacturers of ICs in Australia. There will continue to be a fee and a charge for registration, and the costing model for this is something we've been developing and consulting on (at the time of making this presentation).

Slide 14

This next major obligation might sound obvious – to know what it is you're introducing – but when it comes to knowing all the ingredients in all your products, and what regulatory treatment each of them attracts, it's a bit more of a big deal.

The big difference is that, in the new scheme, you're checking the Category of Introduction for each ingredient, which is a new concept that we'll go into in much more detail here and in other presentations.

Checking your ingredients against our chemical Inventory remains the crucial first step, just like it is now.

The other significant difference in the new scheme is that there will be an offence associated with not knowing what you're introducing (or not having access to the required information from a supplier).

Slide 15

Now we come to the really different aspect: Categorisation. In a nutshell, there are 5 Categories that your introduction can fall into, each with its own criteria and associated regulatory obligations.

Listed introductions are where your chemical is on the Inventory, and your introduction and use are within any and all terms of the Inventory listing, including any conditions. There's a whole separate presentation on the Inventory with details of what the listings will include and how the terms will operate to authorise your introduction and/or confer further obligations.

If your introduction is not Listed, then there are 4 Categories it could fall into. 3 of them are based on the indicative risk profile of your introduction, with associated obligations that are proportionate to that risk.

Very low risk introductions fall into the Exempted category, which requires a once-off post-introduction declaration.

Low risk introductions fall into the Reported category, which requires you to submit a Report before you start introducing.

Medium and high risk introductions fall into the Assessed category, which will create a much smaller cohort of introductions that require risk assessment by us before you get a certificate authorising you to start introducing. This is also the only category that leads to getting your chemical listed on the Inventory.

Finally there remains, as there is now under NICNAS, a separate category for introductions that are for the sole purpose of commercial evaluation. This also requires pre-introduction risk assessment by us, in a shorter time frame, for a more limited authorisation to introduce.

For completeness, I should mention that there's also a category called an Exceptional Circumstances Authorisation. As the name suggests, this is expected to be used only very rarely, and would be issued by the Minister.

Slide 16

Just like now, if you introduce industrial chemicals then you'll have to keep records about them, for 5 years. The records you need to keep will be a bit different, in keeping with the different approach of categorisation.

So you'll need to keep records to show what information you relied on to determine the category of your introductions, and how you worked out your registration level and charge.

If you're introducing cosmetics or cosmetic ingredients, you'll need to keep records relating to animal test data (or the lack thereof).

There may also be specific information requirements on an Inventory listing, or information you're required to give to us in certain circumstances relating to your assessed chemical.

Slide 17

Finally, there are some circumstances in which the Executive Director of AICIS can ask you for information, and you're obliged to give it.

The ED can request any information that you're obliged to keep under the record keeping requirements we talked about in the previous slide.

The ED can request information in relation to your certificate application, or in relation to an evaluation that we do of any industrial chemical in Australia.

You can also be requested to give information as part of monitoring and compliance activities.

If the ED makes a formal request for information that has to be complied with, the request has to be in writing, with a deadline of at least 20 working days.

Slide 18

So here's the wheel of obligations again, summarising which bits are the same as NICNAS, and which bits are changing.

In brief: Registration will be the same, Knowing your introductions will be a bit different, Categorising your introductions is a new thing, Applying for a pre-introduction assessment will be a bit different, Declarations and reports in relation to other introduction categories is new, Record keeping is a bit different, and giving us information when we ask is basically the same.

Slide 19

Now here's a new sounding thing: Evaluation. It sort of is new, and it sort of really isn't.

Evaluation is what we're calling risk assessments that AICIS will do off its own bat, not in response to an introducer's application for a certificate or authorisation.

NICNAS does this sort of thing in a few different ways, each of which has its own particular restrictions and limitations. The new Evaluations framework for AICIS aims to create a flexible framework that provides for a comprehensive program of risk assessment of industrial chemical introductions in Australia, including the ability to respond to emerging issues and new information.

Slide 20

Under the new Evaluations framework, AICIS can respond to a range of triggers.

The biggest source of Evaluations will be ongoing Prioritisation activity, essentially a continuation of the work done under NICNAS's IMAP program, which has to date assessed thousands of chemicals on our Inventory, though under administrative arrangements due to a lack of legislative provisions.

Evaluations could also be triggered by post market monitoring and compliance activity, such as an audit or individual case work.

AICIS will be able to initiate Evaluations in response to nominations from risk managers, such as the ACCC or State and Territory agencies; this can also encompass nominations from the public; or in response to international actions.

Evaluations can occur in response to information we receive from introducers who have obligations to tell us if certain circumstances occur.

Inventory activities that may trigger an Evaluation can be the inclusion of chemicals on the Inventory that were previously regulated by another agency; or the identification of wrongly added or misidentified chemicals on the Inventory.

The Subject of an Evaluation can be, basically, any industrial chemicals. This can include industrial chemicals that are excluded from other obligations, such as naturally-occurring chemicals that do not need to be categorised and don't count for determining your registration charge.

An Evaluation can be based on a class or group of ICs, and it can get specific about a particular Hazard, Exposure or Use, Circumstances of introduction, or a kind of Risk.

When we conduct Evaluations, we can make 'calls for information', asking specific people, such as those who have introduced certain chemicals, for information about those introductions. Those calls for information can, in limited circumstances, be mandatory.

Whilst doing an Evaluation, we can – and sometimes must – consult, be that with certificate holders, the public, or with risk managers.

Slide 21

There's also a range of what can come out at the end of an Evaluation.

We have to publish an Evaluation Statement, and this has to include any risk management recommendations we conclude are necessary. These recommendations will also be published on a Risk Recommendation Register, which will record the progress of those recommendations in terms of actions by risk management agencies.

Our Inventory listings will also include access to any Evaluation statement published for that chemical.

Less frequent outcomes are varying the terms of an assessment certificate or Inventory listing, such as adding, removing or changing a condition of introduction or use.

An Evaluation can also result in AICIS adding a misidentified chemical to the Inventory, adding chemicals that were previously regulated by another agency, or reviewing approval of protection of Confidential Business Information.

Finally, the 'risk manager of last resort' powers I referred to earlier, that we expect will only be used rarely, are the ability to cancel a certificate or remove an Inventory listing, if this is the only way to manage risks associated with the introduction of that IC.

Slide 22

Thank you very much for your attention this far. This overview has covered a lot of ground, and you'll find more explanation and details in our single-topic presentations. We hope this has helped you understand the new scheme, and how we're going to get there. For further information, including guidance material and links to our legislation, please visit our website.